DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 19-050/S-025

Akorn Inc.
1222 West Grand Ave.
Decatur, IL 62522

Attention: James G. Baumann, Jr.
Manager, Regulatory Submissions

Dear Mr. Baumann:

Please refer to your supplemental new drug application dated December 12, 1996, received December 17, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sufenta (sufentanil citrate) Injection.

We acknowledge receipt of your submissions dated July 9, 2001. This submission constituted a complete response to our November 3, 2000, action letter.

This supplemental new drug application provides for additional pediatric use information, and includes revisions to the CLINICAL PHARMACOLOGY, PRECAUTIONS, DOSAGE AND ADMINISTRATION, and INDICATIONS sections of the package insert.

We have completed the review of this supplemental application, as amended, including the final printed labeling submitted on July 9, 2001, and it is approved effective on the date of this letter. The following editorial change should be made at the time of the next printing.

> In the ADVERSE REACTIONS section, Probably Causally Related: Incidence Less than 1%-Derived from clinical trials subsection, add the word "Incidence" before the numbers "0.3% to 1%."

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

> Division of Drug Marketing, Advertising, and Communications, HFD-42
> Food and Drug Administration
> 5600 Fishers Lane
> Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research